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(71) Applicant (for all designated States except US): MEDICAL LASER TECHNOLOGIES LIMITED [GB/GB]; Unit 4, Belleknowes Industrial Estate, Inverkeithing, Fife KY11 1HY (GB).

(72) Inventor; and

- (75) Inventor/Applicant (for US only): COLLES, Michael, John [GB/GB]; Boglesknowe, Hartree by Biggar, Lanarkshire ML12 6JJ (GB).
- (74) Agent: MURGITROYD & COMPANY; 373 Scotland Street, Glasgow G5 8QA (GB).

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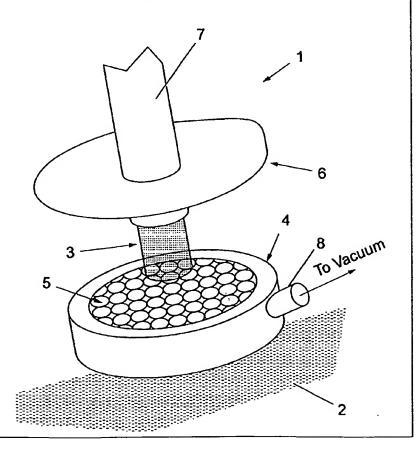
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(54) Title: APPARATUS AND METHOD FOR DELIVERY OF LIGHT TO SKIN

#### (57) Abstract

Improvements to a system for the process of hair removal which employs a collimated laser beam delivered to a target. These improvements include a reflector for reflecting back light scattered from the surface and improving light coupling into the tissue, use of an array of micro lenses for focusing the incident beam, and an annular ring to thin the epidermis and upper dermis to reduce blood volume in the illuminated area, and increase flux density at significant depths.



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1 Apparatus and method for delivery of light to skin 2 3 This invention relates to light delivery and in 4 particular to a apparatus and method for delivery of a 5 beam of light to a target area beneath the surface of 6 7 the skin. 8 Most particularly this invention relates to an 9 apparatus and method designed to improve the delivery 10 11 of laser or other light to targets underneath the skin surface especially, but not solely, to assist in 12 13 optical hair removal. That is, this invention relates 14 to the use of optical based techniques in dermatology for the removal of unwanted stains, pigment, marks, 15 hairs, or other sub-surface features. 16 17 Lasers and, in some cases, other light sources have 18 19 found increasing use in dermatology for the treatment or removal of sub-surface lesions. These techniques 20 have largely been based on the concepts of selective 21 22 photothermolysis. This implies that the laser 23 wavelength is chosen to match a characteristic 24 absorption associated with the target but not with the 25 surrounding tissue. Thus, absorption of the laser

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light and the subsequent heating is largely restricted 1 to that target. In addition, the process also involves choosing the duration of the laser pulse to maximise the temperature of the target before significant conduction to the surrounding tissue can take place. 5 6 For example, a 30 nanosecond pulse from a Nd:YAG laser at  $1.06\mu m$  is strongly and selectively absorbed in the 7 blue-black pigments of common tattoos. Since the 8 9 tattoo pigments accumulate in granules of micron size, such a short pulse is almost wholly used to heat and 10 fragment the granule before significant heating of the 11 surroundings takes place. 12 13 14 More recently techniques have been described which relate to the removal of unwanted hair using lasers. 15 In one approach a Nd:YAG laser similar to the one 16 mentioned above is used. Since there is little or no 17 natural selective absorption at this wavelength, an 18 external chromophore must first be applied and 19 persuaded to migrate down the hair shaft to the base to 20 21 provide an appropriate target. 22 In an alternative approach a ruby laser at 0.694nm is 23 24 In this approach the melanin content of the hair shaft provides the selectively absorbing chromophore. 25 26 27 The ruby laser was introduced many years ago for removal of tattoos. For tattoo removal the laser 28 29 output was "Q-Switched" - that is, the energy was 30 compressed to a pulse of only a few 10's of nanoseconds. Such a pulse, whilst ideal for tattoo 31 granule fragmentation, is neither necessary nor 32 33 desirable for the more thermal process of hair removal. 34 35 For hair removal, the ruby laser is operated in its so-36 called "normal mode" wherein the pulse duration is

3

1 extended to about 1 millisecond. The real target is not the hair itself. Following the selective 2 absorption of the laser light along the buried hair 3 shaft and the heating of the latter, the overall 4 process relies on the conduction of heat from the shaft 5 6 to surrounding tissue, in particular to two zones, the 7 first near the shaft base (papilla); and the second 8 approximately a third of the way down the shaft, known 9 as the bulge. Direct absorption into these zones is possible, and can contribute to their heating since 10 they also contain an enhanced level of melanin. 11 12 zones are believed to contain the cells responsible for 13 hair growth, and damage to them via this process of laser heating should lead to permanent hair removal or 14 15 at least substantially delayed regrowth. 16 A simple approach is to apply light with the required 17 18 level of energy density to an area of skin. 19 is chosen to give sufficient heating to destroy the 20 target zones whilst leaving the surrounding tissue 21 undamaged. In practice this required level lies 22 between 10 and 50 J/cm<sup>2</sup>. 23 24 Various techniques have been used or proposed to assist 25 in improving the efficiency of the process. 26 techniques include precooling of the area, cooling 27 during the process, selective cooling of the epidermis 28 using millisecond cryogen spray, use of optical 29 transmitting gels to improve coupling into the tissue, 30 convex shaped applicators, and devices to draw folds of 31 skin which may receive radiation from either side. 32 33 Whereas there may be both advantages and disadvantages 34 to varying degrees in all of these approaches, it is manifest that there is a need for a beam delivery 35 36 system that addresses the problems of sub-surface

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targeting from both an optical and a biological 1 viewpoint. 2 3 According to a first aspect of the present invention 4 there is provided an apparatus for delivery of a beam 5 of light to a target area beneath the surface of the skin comprising means to deliver a collimated light 7 beam, and light delivery means to increase the light 8 energy density at said target area while minimising the 9 light energy density at the surface of the skin. 10 11 Preferably said means to improve delivery comprises 12 13 means to improve effective light coupling into tissue. Said means to improve effective light coupling may 14 comprise recovery means to recover light reflected on 15 incidence with the skin. 16 17 Said recovery means may comprise a reflective surface. 18 19 Preferably the apparatus comprises means to thin the 20 21 skin above the target area. Said means may stretch the skin. 22 23 24 Preferably the apparatus comprises means to reduce local blood flow in the target area. 25 26 27 Preferably the means to stretch the skin acts also to reduce the local blood flow. 28 29 Preferably the apparatus comprises means to subject the 30 area adjacent the target area to vacuum suction. 31 32 33 Said means may comprise a member adapted to be sealed 34 to the skin and to subject the area of skin surrounding 35 the target area to a vacuum. 36

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Preferably said member has an annular channel. Said channel may be ring shaped or oval. 2 Preferably said channel is adapted to be positioned 3 with the channel opening in contact with the skin. 4 5 Preferably the apparatus comprises means to increase 6 light flux density at the depth of the target. Said 7 means may redistribute an incident collimated beam 8 prior to its incidence with the skin. 9 10 Said redistribution means may comprise an array of 11 Preferably said lenses are of short focal 12 length. Preferably said array is selected to increase 13 the flux density at a nominated depth. 14 15 16 Preferably the apparatus comprises recovery means to recover light reflected on incidence with the skin; 17 means to thin the skin above the target; and means to 18 increase light flux at the depth of the target. 19 20 21 Preferably the light beam is a laser light beam. 22 The apparatus may further include known techniques such 23 as tissue precooling and/or selective cooling of the 24 epidermis and/or use of optical transmitting gels 25 and/or convex shaped applicators and/or devices to draw 26 folds of skin which may receive radiation from either 27 side and/or other features already known. 28 29 According to a second aspect of the present invention 30 there is provided a method for delivery of a beam of 31 light to a target area beneath the surface of the skin 32 33 comprising the step of using an apparatus according to the first aspect of the invention.

36 According to a further aspect of the present invention

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1	there is provided a method for delivery of a beam of
2	light to a target area beneath the surface of the skin
3	comprising the steps of directing a collimated light
4	beam onto the surface of the skin, and using a light
5	delivery means to increase the light energy density at
6	said target area while minimising the light energy
7	density at the surface of the skin.
8	
9	Embodiments of the present invention will now be
10	described by way of example only with reference to the
11	accompanying drawings in which:
12	
13	Figure 1 shows a apparatus in accordance with an
14	aspect of the present invention.
15	•
16	Figures 2a and 2b illustrate the effect on fluence
17	at the skin surface and at a given depth beneath
18	the surface, of increasing the area of surface
19	illumination of the skin;
20	
21	Figures 2c and 2d also illustrate the effect on
22	fluence at the skin surface and at a given depth
22 23	fluence at the skin surface and at a given depth beneath the surface, of increasing the area of
23	beneath the surface, of increasing the area of surface illumination;
23 24 25 26	beneath the surface, of increasing the area of surface illumination;  Figure 2e is a graphical representation of the
23 24 25 26 27	beneath the surface, of increasing the area of surface illumination;  Figure 2e is a graphical representation of the rate of increase of the effective fluence at depth
23 24 25 26	beneath the surface, of increasing the area of surface illumination;  Figure 2e is a graphical representation of the
23 24 25 26 27 28 29	beneath the surface, of increasing the area of surface illumination;  Figure 2e is a graphical representation of the rate of increase of the effective fluence at depth with increase of surface beam diameter;
23 24 25 26 27 28 29 30	beneath the surface, of increasing the area of surface illumination;  Figure 2e is a graphical representation of the rate of increase of the effective fluence at depth with increase of surface beam diameter;  Figures 3a and 3b show a beam focusing
23 24 25 26 27 28 29 30 31	beneath the surface, of increasing the area of surface illumination;  Figure 2e is a graphical representation of the rate of increase of the effective fluence at depth with increase of surface beam diameter;  Figures 3a and 3b show a beam focusing arrangements in accordance with an aspect of the
23 24 25 26 27 28 29 30 31 32	beneath the surface, of increasing the area of surface illumination;  Figure 2e is a graphical representation of the rate of increase of the effective fluence at depth with increase of surface beam diameter;  Figures 3a and 3b show a beam focusing
23 24 25 26 27 28 29 30 31 32 33	beneath the surface, of increasing the area of surface illumination;  Figure 2e is a graphical representation of the rate of increase of the effective fluence at depth with increase of surface beam diameter;  Figures 3a and 3b show a beam focusing arrangements in accordance with an aspect of the present invention;
23 24 25 26 27 28 29 30 31 32 33	beneath the surface, of increasing the area of surface illumination;  Figure 2e is a graphical representation of the rate of increase of the effective fluence at depth with increase of surface beam diameter;  Figures 3a and 3b show a beam focusing arrangements in accordance with an aspect of the present invention;  Figure 4 illustrates means for recapturing
23 24 25 26 27 28 29 30 31 32 33	beneath the surface, of increasing the area of surface illumination;  Figure 2e is a graphical representation of the rate of increase of the effective fluence at depth with increase of surface beam diameter;  Figures 3a and 3b show a beam focusing arrangements in accordance with an aspect of the present invention;

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1 Figure 5 shows an annular ring in accordance with 2 an aspect of the present invention. 3 Referring to the drawings, this apparatus, generally 4 5 designated 1 is designed to provide a combination of 6 both optical and mechanical means of improvement of the sub-surface flux density of a beam delivered by a beam 7 8 delivery system to the target areas. Although this apparatus has its origins in improvements related to 9 beam delivery for hair removal, other optical processes . 10 requiring selective sub-surface damage may benefit. 11 12 A beam delivery system normally comprises a light 13 source and means for its delivery to a target area. A 14 first improvement to this system is the provision of a 15 sealed annular ring 4 as shown in Figure 5. 16 17 annular ring is placed adjacent the tissue surface 2 18 above the target: The region of surface skin in the annulus is subject to a vacuum by connection of a 19 vacuum pump to vacuum outlet 8 and is thus drawn 20 upwards to form raised areas 11. In one dimension this 21 is similar to proposals for obtaining a fold of tissue 22 23 to allow transillumination. However the instant configuration takes advantage of the fact that dermal 24 blood is taken towards the region 11 under vacuum in 25 the direction of arrows 10 and thus away from the 26 central circular core area 12. 27 28 29 Although the ruby laser wavelength corresponds to a minimum in the absorption spectrum of blood, residual 30 absorption of blood remains a competing unwanted factor 31 in the utilisation of the laser light. 32 Thus reduction of local blood volume due to adjacent vacuum suction 33 provides an important advantage. 34 35 36 A second and more significant effect is that the

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1 drawing up into the annulus of a small amount of tissue 2 13 effectively stretches the skin 2 throughout the circular core 12. Even mild stretching of around 10% 3 4 of the diameter - 2mm in Figure 5 where the central 5 area has a diameter of 20mm - translates to a thinning 6 of the epidermis and upper dermis of 20%. Since the reduction in light flux with depth into the skin is 7 8 exponential this thinning provides an increase in flux 9 density of as much as 80% at a depth of 3mm corresponding to the depth of the papilla. 10 effect, in conjunction with the reduction of the local 11 . blood volume, reduces the required incident flux 12 density by a significant factor. These effects also 13 14 improve the selectivity of the process. 15 This aspect of the invention is thus directed 16 17 principally at providing a physical means of reducing 18 beneficially both the blood content of the tissue immediately below the exposed area, and the thickness 19 20 through which light must penetrate to reach structures 21 at depths of several millimetres. 22 23 Both these effects, that is the biological and the 24 physical, combine to improve the fraction of light 25 fluence (energy per unit area) at the required depth 26 for a given fluence at the surface. 27 28 Usually if the target structures are at some 29 significant depth into tissue, a problem arises in trying to balance the need for a minimum fluence at 30 31 depth required to effect the necessary damage, whilst 32 sparing structures nearer the surface that normally see a significantly higher fluence. This aspect of the 33 34 invention acts directly to improve this situation and 35 thus helps in sparing surface tissue and components. 36

1 A handpiece incorporating such a ring 4 has its most

- 2 immediate application in a process such as hair removal
- 3 where selective damage to the follicles 2-4mm deep is
- 4 required. Other applications, for example the
- 5 visualisation of dermal blood vessel anatomy for
- 6 diagnostic purposes would also benefit.

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- 8 The influence of light scattering in tissue is to
- 9 substantially increase the volume of tissue
- 10 experiencing some of the light compared with the
- initially exposed area. The larger the initial area,
- 12 the less this affects the fluence at a given depth
- other than near the perimeter of the area.

14

- 15 This phenomenon is best understood by reference to
- 16 Figures 2a and 2b.

17

- 18 In Figure 2a the spread of the energy present in the
- 19 beam, that is, the expansion of the beam due to
- 20 scattering, is indicated approximately by following a
- 21 line 30 representing the average direction of scattered
- 22 photons. The energy incident on the surface is within
- 23 an area 20 of 1mm<sup>2</sup>, but at a depth of 3mm 50% of the
- 24 incident energy can be found within a much larger area
- 25 21 of 1cm<sup>2</sup>. Thus the surface fluence is reduced by
- about a factor of 200. (This assumes that no
- absorption takes place.)

- 29 If a second area 22, adjacent to the first area 20 and
- 30 also of 1 mm<sup>2</sup>, is illuminated with equal energy, then
- 31 the fluence (energy density) on the surface remains
- 32 constant. It can be seen from Figure 2b that at depth
- 33 the energy from the second source in area 23 very
- 34 largely overlaps that of the first source in area 21.
- 35 Thus the fluence at depth has almost doubled for no
- 36 change in surface fluence.

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Figures 2c and 2d show the same effect but with sample 1 fluences typical of laser hair removal. 2 3 This process continues with the fraction of the surface 4 5 fluence effective at depth increasing with size of illuminated area. The rate of increase slows to give a 6 7 constant fraction when the illuminated area of the surface is several cm2. This function is sketched in 8 Figure 2e, in which line 40 shows the fluence at 3mm 9 depth (in J/cm²) plotted against the beam diameter at 10 11 the surface (in mm). 12 The numbers used in this example are illustrative only 13 but are close to those encountered in skin. 14 15 case of hair removal, a target is approximately 3 mm deep and therefore a certain level of fluence will be 16 17 required at that depth to achieve the required 18 therapeutic effect. 19 20 This therapeutic fluence is determined by the 21 absorption of light from lasers such as ruby and 22 alexandrite into the melanin within and around the follicle. The epidermis and upper dermis, however, 23 24 contain the same absorbing chromophore as that present 25 in the target. Since it is desirable to spare the epidermis and upper dermis from damage, and these occur 26 27 nearer the surface, it is clear that any means by which the ratio of fluence at a depth compared with surface 28 fluence can be increased offers an improvement in 29 30 efficacy and safety. 31 32 An approach taught in current practice is to use large areas of illumination. However this novel approach, 33 34 and the second aspect of the invention, is to use a lens 15 to sharply focus the incident beam 3 to a point 35 36 16 around 3 mm below the surface 2 as shown in Figure

11 1 Although there are many scattering events as light 2 moves through the tissue, with the consequences outlined above, each event scatters light in a 3 predominantly forward direction. A sharply focused 4 beam therefore offers some counteraction to the spread 5 induced by scattering. 6 7 8 Unfortunately, to focus the whole beam from a pulsed laser such as ruby or alexandrite presents a serious 9 safety hazard; the slightest incorrect positioning of 10 the focal point would substantially increase the 11 coherent fluence at the surface and lead to severe 12 13 damage. 14 Figure 3b shows an arrangement which overcomes this 15 disadvantage by passing the large area collimated beam 16 17 3 through an array 5 of small micro lenses 5a. These 18 lenses are of short focal length. The focusing function of this array 5 is estimated to double the 19 20 sub-surface flux at point 17. There is insufficient energy falling within the acceptance area of an 21 22 individual lens 5a to present a safety hazard. 23 A third aspect of the invention addresses the issue of 24 light coupling into tissue. As mentioned above, the 25 use of a gel has been suggested as a way of improving 26 light coupling. Since the tissue surface is 27 microscopically uneven, applying a gel - and thus 28 essentially smoothing the surface profile to one of 29 near normal incidence to the beam - would indeed help

near normal incidence to the beam - would indeed help to reduce the reflection losses associated with the refractive index difference between tissue and air. Unfortunately this technique does not really address the reason for the 'apparent' high reflectivity of tissue.

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The greater portion of the apparent reflected light is 1 2 caused not by index mismatch but rather by transmission 3 into the tissue followed by scattering into a backward direction and finally re-emergence. 4 5 Although each scattering event is predominantly in the 6 7 forward direction, there are, on average, some 200 such events per mm penetration. As described earlier some . 8 50% of the incident energy contributes to the fluence 9 at depth whilst the remaining 50% is scattered in all-10 the other directions. A half of this, that is 25% of 11 the total, actually finds its way out of the tissue, 12 contributing to the apparent reflected energy. 13 figure of 25% is approximate and depends on the nature 14 15 of the tissue. In skin it can also vary between individuals and on sites on the same individual. 16 However, the figure usually is between 20% and 40%. 17 18 19 This aspect of the invention seeks to provide means of capturing this effectively reflected light by using a 20 21. mirror surface 6 around the handpiece 7 and thus 22 returning the light to the tissue surface 2 once more. 23 This is shown in Figure 4. The area of surface that is the source of this back scattered light is larger than 24 25 the original illuminated area, and the emerging ray directions 18 are spread widely. Under these 26 27 circumstances, only limited focusing of the light to be 28 returned to the tissue is possible. This is achieved 29 using a mirror surface 6 of a parabolic form. 30 simpler hemispherical shape or a conical section are 31 alternatives which give adequate advantage. 32 Irrespective of shape, the action of returning the back scattered light to the tissue surface effectively 33 34 provides an increase in overall coupling, and thus a reduction in the applied energy required to reach a 35

therapeutic level. This reduction is estimated to be

13

1 around 20% and therefore an initial requirement of, for 2 example, a fluence of 20 J/cm<sup>2</sup> at the surface 2 would be reduced to around 16 J/cm<sup>2</sup>. 3 In summary, the embodiment shown in Figure 1 shows an 5 6 apparatus 1 incorporating a combination of the improvements outlined above. This apparatus 1 includes 7 means 4 for drawing up an annulus of tissue, thereby 8 both stretching and thinning the central zone above a 9 10 This central zone is illuminated with a collimated laser beam 3 passing through an array of 11 micro lenses 5. Typically these lenses may be 1mm in 12 diameter and have a focal length of around 10mm. 13 delivery handpiece 7 is provided with a means 6 of 14 15 reflecting back any scattered light returning from the tissue surface. 16 17 This embodiment incorporates all the improvements 18 described. Each individual improvement, that is the 19 20 annular ring 4, the array of micro lenses 5 and the 21 reflector 6 may be separately applied in other simpler 22 embodiments without detracting from their individual 23 novelty. 24 25 Each individual improvement may also be combined with other established methods such as tissue precooling. 26 Other techniques, for example, for stretching the skin, 27 28 would be included in the general principles outlined 29 here. 30 The embodiment described above offers significant 31 32 advantages to the process of hair removal with lasers or other optical means. Specifically these include a 33 34 change in the distribution of light to increase the

flux density at significant depths of, for example, between 1 and 3 millimetres, a reduction in the blood

35

Ţ	volume in the illuminated area and an increase in the
2	effective light flux coupled to the skin. Thus
3	selectivity is improved and the optical energy from the
4	laser or other source is reduced. The embodiment shows
5	specific means for achieving these advantages.
6	
7	
8	Improvements and modifications may be made to the above
9	without departing from the scope of the invention.

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		15
1	CLA	IMS .
2	1.	An apparatus for delivery of a beam of light to a
3		target area beneath the surface of the skin
4		comprising:
5		
6		a collimated light beam source; and
7		
8		light delivery means to increase the light energy
9		density at said target area while minimising the
10		light energy density at the surface of the skin.
11		
12	2.	An apparatus as claimed in Claim 1 wherein said
13		delivery means comprises a reflective surface
14		adapted to recover light reflected away from the
15		skin on incidence with the skin and to redirect
16		said reflected light towards the skin.
17		
18	3.	An apparatus as claimed in any preceding claim
19		wherein said delivery means comprises means to
20		stretch the skin above the target area.
21		
22	4.	An apparatus as claimed in Claim 3 wherein said
23		delivery means comprises means to subject an area
24		of skin adjacent to the skin above the target area
25		to vacuum suction.
26	_	
27	5.	An apparatus as claimed in Claim 4 wherein said
28		delivery means comprises an annular channel member
29		adapted to be sealed to the skin.
30	-	
31	6.	An apparatus as claimed in Claim 5 wherein said

An apparatus as claimed in Claim 5 wherein said 6. channel is ring shaped or oval or of other shape.

32 33

An apparatus as claimed in Claim 5 or Claim 6 34 7. wherein said channel is adapted to be positioned 35 36 with the channel opening in contact with the skin. WO 98/52481

		16
1	8.	An apparatus as claimed in any preceding claim
2		wherein said delivery means comprises means to
3	-	redistribute an incident collimated beam prior to
4		its incidence with the skin.
5		
6	9.	An apparatus as claimed in Claim 8 wherein said
7		redistribution means comprises an array of lenses.
8		·
9	10.	An apparatus as claimed in Claim 9 wherein said
10		lenses are of short focal length.
11		
12	11.	An apparatus as claimed in Claim 9 or Claim 10
13		wherein said array is adapted to increase the flux
14		density at a predetermined depth.
15		
16	12.	An apparatus as claimed in any preceding claim
17		wherein the light beam is a laser light beam.
18		
19	13.	An apparatus as claimed in any preceding claim
20		further comprising means for precooling the tissue
21		and/or means for selective cooling of the
22		epidermis and/or devices to draw folds of skin
23		which may receive radiation from either side.
24		
25	14.	A method for delivery of a beam of light to a
26		target area beneath the surface of the skin
27		comprising the step of using an apparatus
28		according to any preceding claim.
29		•
30	15.	A method for delivery of a beam of light to a
31		target area beneath the surface of the skin
32		comprising the steps of:
33		
34		directing a collimated light beam onto the surface
35		of the skin; and

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1		using a light delivery means to increase the light
2		energy density at said target area while
3		minimising the light energy density at the surface
4		of the skin.
5.		···
.6	16.	A method as claimed in Claim 15 wherein a
7		reflective surface is used to recover light
8		reflected away from the skin on incidence with the
. 9		skin and to redirect said reflected light towards
10		the skin.
11		
12	17.	A method as claimed in any of Claims 15 to 16
13		wherein the skin is stretched above the target
14		area.
15		
16	18.	A method as claimed in Claim 17 wherein an area of
17		skin adjacent to the skin above the target area is
18		subjected to vacuum suction.
19		
20	19.	A method as claimed in Claim 18 wherein a vacuum
21		member comprising an inverted annular channel is
22		placed around the target area and the vacuum
23		member is evacuated to draw the skin into the
24		annular channel.
25		
26	20.	A method as claimed in any one of Claims 15 to 19
27		wherein said collimated light beam is passed
28		through an array of coplanar lenses positioned
29		above the skin surface.
30		·
31	21.	A method as claimed in Claim 20 wherein said
32	•	lenses are microlenses of short focal length.
33		
34	22.	A method as claimed in Claim 20 or Claim 21
35		wherein said array is adapted to increase the flux
36		density at a predetermined depth below the skin

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1		surface.
2		
3	23.	A method as claimed in Claim 22 wherein said
4		predetermined depth is between 1 and 5 mm,
5		preferably between 2 and 4 mm.
6		•
7	24.	A method as claimed in any one of Claims 15 to 23
8		wherein the light beam is a laser light beam.
9		
10	25.	A method as claimed in any preceding claim further
11		comprising the steps of precooling the tissue
12		and/or selective cooling of the epidermis and/or
13		use of optical transmitting gels and/or use of
14		convex shaped applicators and/or use of devices to
15		draw folds of skin which may receive radiation
16		from either side.
17		

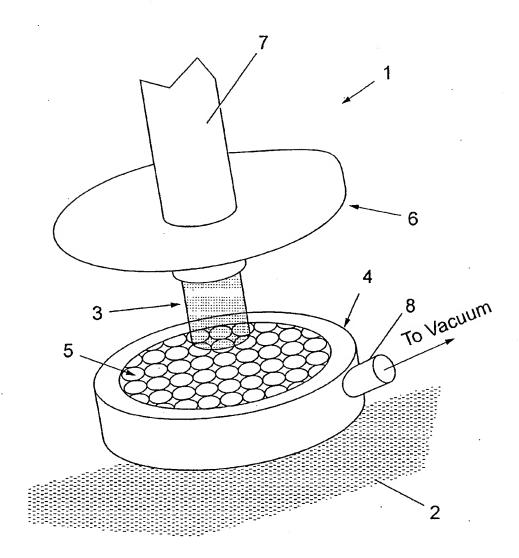
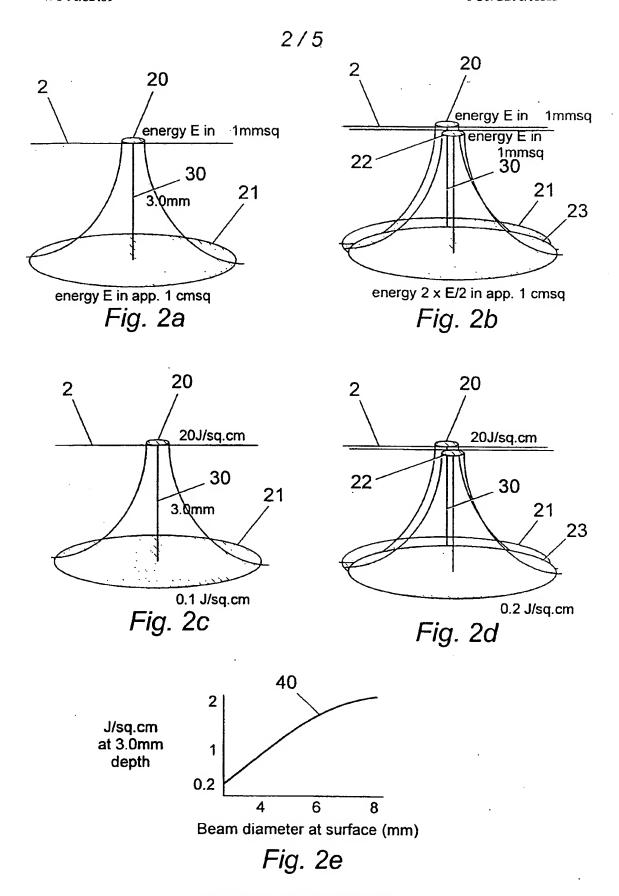
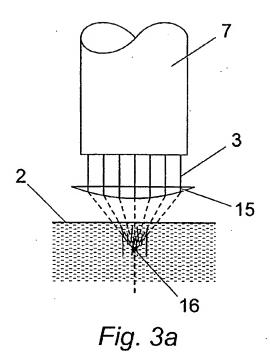


Fig. 1



**SUBSTITUTE SHEET (RULE 26)** 



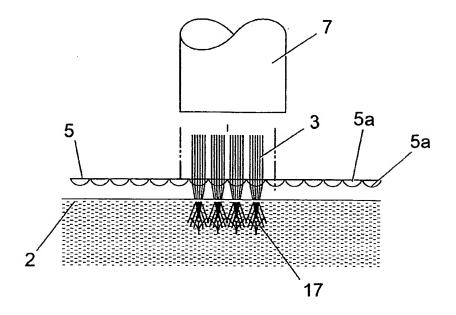


Fig. 3b

**SUBSTITUTE SHEET (RULE 26)** 

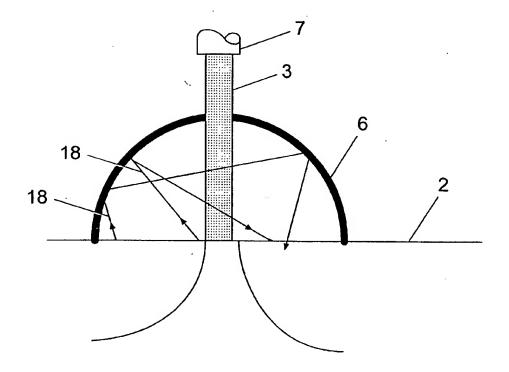


Fig. 4

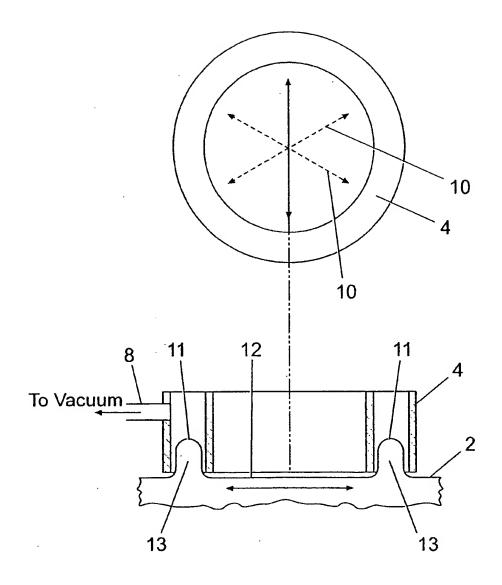


Fig. 5

International Application No PCT/GB 98/01523

A CLASSII IPC 6	FICATION OF SUBJECT MATTER A61B17/41		
According to	o International Patent Classification (IPC) or to both nutional classific	ntion and IPC	
B. FIELDS	SEARCHED	· · · · · · · · · · · · · · · · · · ·	
Minimum do IPC 6	ocumentation searched (classification system followed by classification A61B A61N	an symbols)	
Documental	tion searched other than minimum documentation to the extent that a	uch documents are included in the fields sea	rehed
Electronic d	lata base consulted during the international search (name of data ba	use and, where practical, search terms used)	
C. DOCUM	ENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the re	levant passages	Relevant to daim No.
X	US 5 595 568 A (ANDERSON) 21 Jan	nuary 1997	1-3,12, 13
	see abstract see column 4, line 50 - column 5 see column 4, line 50 - column 5 see column 5, line 63 - column 6 see column 6, line 42 - line 56	5, line 32	
X	US 5 546 214 A (BLACK) 13 August see abstract	1996	1,2
х	WO 84 02644 A (WEISSMAN) 19 July see abstract	y 1984	1
		-/	
X Fui	rther documents are listed in the continuation of box C.	X Patent family members are listed	in annex.
"A" docum	nategories of cited documents :	T later document published after the inte or priority date and not in conflict with cited to understand the principle or th	the application but
'E' earlier filing	idered to be of particular relevance r document but published on or after the international   date - nent which may throw doubts on priority claim(s) or	invention  "X" document of particular relevance; the cannot be considered novel or cannot involve an inventive step when the do	t be considered to
whice citati "O" docur	th is clied to establish the publication date of another ion or other special reason (as specified) ment referring to an oral disclosure, use, exhibition or a means	"Y" document of particular relevance; the cannot be considered to involve an indocument is combined with one or ments, such combination being obvious	plaimed invention ventive step when the ore other such docu-
.b. qocar	ment published prior to the international filing date but than the priority date claimed	in the art. "a" document member of the same patent	
	e actual completion of the international search  30 July 1998	Date of mailing of the international see	uch report
	d mailing address of the ISA European Patent Office, P.B. 5818 Patentiaan 2 NL - 2280 HV Rijswijk	Authorized officer	
	Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Taccoen, J-F	

International Application No
PCT/GB 98/01523

		PC1/GB 90/01323
	ntion) DOCUMENTS CONSIDERED TO BE RELEVANT	In the state No.
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to olaim No.
P,X	US 5 735 844 A (ANDERSON) 7 April 1998 see abstract; figures 2A,2B,3B see column 2, line 6 - line 47 see column 5, line 21 - column 6, line 36 see column 14, line 5 - line 67	1-13
P,X	US 5 653 706 A (ZAVISLAN) 5 August 1997 see abstract see column 1, line 31 - line 52	1-3
	<u>.</u>	

International application No. PCT/GB 98/01523

Box i	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This Inte	mational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X	Claims Nos.: 14-25 because they relate to subject matter not required to be searched by this Authority, namely:  Rule 39.1(4)
2.	Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This Inte	mational Searching Authority found multiple inventions in this international application, as follows:
1.	As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.	As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark	The additional search fees were accompanied by the applicant's protest.  No protest accompanied the payment of additional search fees.

Information on patent family members

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